Serial No.10/591,040 Filed: August 29, 2006

#### **REMARKS**

With entry of the present amendment, claims 1 to 11 are pending. Claims 7 to 11 are new. No claims have been canceled. Claims 1 to 3, 5, and 6 have been amended. No new matter is believed to be presented by the foregoing amendments.

Claim 1 has been amended to more particularly define "NK4" as being a polypeptide having the amino acid sequence of SEQ ID NO: 2 and also to more particularly define the solutions used for solubilizing and renaturing the polypeptide. Support for this amendment is found in the Sequence Listing and in the specification at page 2, lines 14 to 19, page 4, lines 17 to 26, and page 5, line 22.

Amendments of an editorial nature have been made to claims 2, 3, 5, and 6.

Claims 7 to 11 have been added to more particularly define the present invention. Support for claim 7 is in the specification at page 2, line 21. Support for claims 8 and 9 is in the specification at page 4, lines 17 to 26. Support for claims 10 and 11 is in the specification at Example 2.

Entry of this amendment and reconsideration of the claims, as amended and in view of the following remarks, is requested.

# The Section 112, First Paragraph, Rejection

Claims 1 to 6 were rejected under Section 112, first paragraph, as lacking enablement because the claims did not specify a denaturing agent. This rejection has been overcome by the present amendment to the claims.

For the foregoing reason, the rejection of claims 1 to 6 under Section 112, first paragraph, is overcome and should be withdrawn.

# The Section 112, Second Paragraph, Rejection

Claims 1 to 6 were rejected under Section 112, second paragraph, as being indefinite in that the term "NK4" is allegedly vague. This rejection has been overcome by the present amendment to the claims in which the term has been replaced with "a polypeptide having the amino acid sequence of SEQ ID NO: 2". SEQ ID NO: 2 corresponds to amino acids 32 to 478 of

the NK4 polypeptide with the exception that a Met residue has been added at the N-terminal and the amino acid that corresponds to the Gln residue at position 32 of NK4 has been replaced with Ser (see page 6, lines 6 to 9, of the specification).

Claims 5 and 6 were also rejected as being indefinite because the phrase "GSH-modified NK4" was vague as the claims did not recite how GSH is introduced in the claimed method. This has been overcome by the present amendment to the claims.

For the foregoing reasons, the rejections under Section 112, second paragraph, are overcome and should be withdrawn.

#### The Section 103 Rejection

Claims 1 and 3 were rejected as being obvious over the combined disclosures of US 2004/0052777 (Nesbit et al.) and Stahl et al., *Int. J. Exp. Path.*, 81:17-30 (2000). According to the Examiner, Nesbit et al. discloses the production of kringle-containing fragments of protein in *E. coli* and purifying them from inclusion bodies using a potassium phosphate-buffered solution at pH 7.4 for solubilization and renaturation but does not disclose the production of NK4 in *E. coli* and the purification therefrom; however, Stahl et al. discloses the production of NK4 in *E. coli* and the purification thereof from inclusion bodies, albeit using a different scheme. The Examiner alleges that one skilled in the art would have been motivated to produce NK4 in *E. coli* as described by Stahl et al. and then purify the NK4 using the method of Nesbit et al.

Applicants respectfully traverse the Examiner's rejection. The Examiner has mis-read Stahl et al. Nowhere is Stahl et al. is there any disclosure relating to NK4. As acknowledged by the Examiner, Nesbit et al. does not contain any disclosure relating to NK4 either. As there is no disclosure whatsoever in the cited references relating to NK4 and as different polypeptides require different conditions for renaturation, one of skill in the art would not have combined the disclosures of the cited references and arrived at applicants' invention.

For the foregoing reasons, the rejection of claims 1 and 3 under Section 103 is traversed and should be withdrawn.

# **CONCLUSION**

The foregoing amendment is fully responsive to the Office Action issued June 18, 2008. Applicants submit that claims 1 to 11 are allowable. Early and favorable consideration is earnestly solicited.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney is respectfully solicited.

Applicants believe that no fee is due with this communication. However, should the Patent Office determine that a fee is owed, or a credit is due to applicant, the Patent Office is hereby authorized to charge any required fees, including any extension of time and/or excess claim fees, or credit any overpayment, to applicant's Deposit Account 08-2525 as appropriate.

Respectfully submitted,

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